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| APPLICATION NO.  | FILING DATE                      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|----------------------------------|----------------------|-------------------------|------------------|
| 09/870,023   | 05/30/2001                       | Charles L. Branch    | 4002-2533               | 9301             |
| 75   | 90 04/08/2003                    |                      |                         |                  |
| James B. Myers Jr. Woodard, Emhardt, Naughton, Moriarty & McNett Bank One Center/Tower |                                  |                      | EXAMINER                |                  |
|  |                                  |                      | PHILOGENE, PEDRO        |                  |
| 111 Monument<br>Indianapolis, IN   | Circle, Suite 3700<br>46204-5137 |                      | ART UNIT                | PAPER NUMBER     |
| maianapons, n  | 102013137                        |                      | 3732                    | 1/               |
| ٠  |                                  |                      | DATE MAILED: 04/08/2003 | , 15             |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No.   | Applicant(s)   | MF                  |  |  |
|---|---|---|--|---------------------|--|--|
|   |   | 09/870,023  | BRANCH ET AL.  | 1111                |  |  |
|   | , Office Action Summary   | Examiner  | Art Unit   |                     |  |  |
|   |   | Pedro Philogene   | 3732   |                     |  |  |
|   | The MAILING DATE of this communicat   |   |  | dress               |  |  |
| Period fo                                       |   |   |  |                     |  |  |
| THE - Exte after - If the - If NC - Failu - Any | ORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNICA nsions of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communical period for reply specified above is less than thirty (30) day of period for reply is specified above, the maximum statutor are to reply within the set or extended period for reply will, freply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b). | TION.  CFR 1.136(a). In no event, however ation.  ys, a reply, within the statutory minimy period will apply and will expire Statute, cause the application to be | er, may a reply be timely filed  num of thirty (30) days will be considered timel  X (6) MONTHS from the mailing date of this collection  ecome ABANDONED (35 U.S.C. § 133). | y.<br>ommunication. |  |  |
| 1)⊠   | Responsive to communication(s) filed  | on <u>20 February 2002</u> .  |  |                     |  |  |
| 2a)⊠  | This action is FINAL. 2b)[  | This action is non-fina   | al.  |                     |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |   |  |                     |  |  |
| ,   | closed in accordance with the practice  |   |  | ··-= <b>·-</b>      |  |  |
| ·   | ion of Claims  Claim(c) 63 105 in/are pending in the a  | naliantina  |  |                     |  |  |
| •   | Claim(s) <u>63-105</u> is/are pending in the a  | •   | ion  |                     |  |  |
|   | 4a) Of the above claim(s) is/are w  | nundrawn from considerat  | ion.   |                     |  |  |
| ·   | Claim(s) is/are allowed.  |   |  |                     |  |  |
|   | Claim(s) <u>63-105</u> is/are rejected.   |   |  |                     |  |  |
| 7) 📙  | Claim(s) is/are objected to.  |   |  |                     |  |  |
| -   | Claim(s) are subject to restriction ion Papers  | and/or election requirem  | ent.   |                     |  |  |
|   | The specification is objected to by the Ex  | r <b>ami</b> nos  |  |                     |  |  |
| •   | The drawing(s) filed on is/are: a)  |   | to by the Evenines   |                     |  |  |
| 10)   | Applicant may not request that any objection  | •   | •  |                     |  |  |
| 11)[]   | The proposed drawing correction filed on  | Ŧ·, *   | , ,  | ~                   |  |  |
| 11/   | If approved, corrected drawings are require   |   | •  | <b>71.</b>          |  |  |
| 12)□ .  | The oath or declaration is objected to by   | • •   | 11.  |                     |  |  |
| •   | inder 35 U.S.C. §§ 119 and 120  | and Examinor.   |  |                     |  |  |
| _   | Acknowledgment is made of a claim for   | foreign priority under 25 L   | 1 C C S 110(a) (d) as (6)  |                     |  |  |
|   | ☐ All b)☐ Some * c)☐ None of:   | ioreigir priority titider 33 t  | J.S.C. § 119(a)-(u) of (i).  |                     |  |  |
| a)ر   |   | umanta haya haan raasiy   | ad   |                     |  |  |
|   | <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>   |   |  |                     |  |  |
|   |   |   |  | <b>0</b> 1          |  |  |
| * 8   | 3. Copies of the certified copies of the application from the Internation for the attached detailed Office action for   | nal Bureau (PCT Rule 17   | .2(a)).  | Stage               |  |  |
| 14) 🗌 A   | cknowledgment is made of a claim for do   | omestic priority under 35   | U.S.C. § 119(e) (to a provisional  | application).       |  |  |
| `   | ) ☐ The translation of the foreign langua<br>Acknowledgment is made of a claim for d  |   |  |                     |  |  |
| Attachment                                      | c(s)  |   |  |                     |  |  |
| 2) Notice                                       | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PTO-9<br>nation Disclosure Statement(s) (PTO-1449) Paper  | 48) 5) 🔲 N  | nterview Summary (PTO-413) Paper No(<br>otice of Informal Patent Application (PTO<br>ther:   |                     |  |  |
| tent and Tr                                     | ademark Office  | 16: 0 · · · · · · · · · · · · · · · · · ·   |  |                     |  |  |

Art Unit: 3732

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## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 63-105 are rejected under 35 U.S.C. 102(e) as being anticipated by Bianchi et al. (6,033,438).

With respect to clam 1, Bianchi et al disclose a spinal fusion implant (500,500') comprising a bone portion having an upper bone engaging surface, a lower bone engaging surface; as best seen in FIGS. 10-14, a first side wall and an opposite second side wall extending between the upper and lower bone engaging surfaces; as seen in FIGS. 8,9; the first side wall having a first generally planar surface, a second generally planar surface and a concave surface there between; as set forth in column 8, lines 43-51.

With respect to claim 2, Bianchi et al disclose an implant wherein the bone portion is formed from a donor bone segment defining at least a portion of a medullary canal and the concave surface defines a portion of the medullary canal; as set forth in the abstract; as set forth in column 5, lines 47-56.

With respect to claim 3, Bianchi et al disclose an implant wherein the upper and lower bone engaging surfaces include a roughened surface (542,632).

Art Unit: 3732

With respect to claim 4, Bianchi et al disclose an implant wherein the roughened surface includes grooves; as set forth in column 7, lines 50-64.

With respect to claim 63, Bianchi et al disclose a spinal fusion implant comprising an elongate bone portion defining a longitudinal axis, and having a generally rectangular cross-section transverse to the longitudinal axis; as set forth in column 8, lines 43-51, the bone portion comprising a first bone engaging surface, a second bone engaging surface; and a first side wall extending between the first and second bone engaging surfaces, as set forth in column 8, lines 13-27, wherein the first side wall comprises a concave surface; as best seen figures.

With respect to claims 64-81,89-92,Bianchi et al disclose all the limitations, the shape of the sidewalls, ridges or teeth on the engaging surface, an end wall having a recess or a threaded bore, or a groove, adapted to engage an implant holder; as set forth in columns 7-8, lines 1-68 and in column 8, lines 43-51.

With respect to claim 82, Bianchi et al disclose a spinal fusion implant comprising an elongate bone portion defining a longitudinal axis, as best seen in FIG.16, and comprising, a first side wall comprising a concave surface, a second side wall comprising a convex surface generally parallel to the concave surface; as best seen in Fig.13, a first bone engaging surface positioned between the first and second side walls, and a second bone engaging surface opposite the first bone engaging surface; as best seen in Fig. 8-14, wherein at least one of the first or second bone engaging surfaces comprises ridges or teeth; as set forth in column 7, lines 50-64.

Art Unit: 3732

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With respect to claim 83, Bianchi et al disclose all the limitations, as best seen in FIGS. 13.

With respect to claim 84, Bianchi et al disclose a system for spinal fusion of adjacent vertebrae, the system comprising a pair of spinal implants; as best seen in FIGS. 8,9, the spinal implants comprising an elongate bone portion defining a longitudinal axis and having a generally rectangular cross section transverse to the longitudinal axis; as set forth in column 8, lines 43-51; a first bone engaging surface, a second opposite bone engaging surface, and a first side wall extending between the first and second bone engaging surfaces, the first side wall comprising a concave portion (FIGS.8,9) the pair of implants are positioned in an intervertebral space whereby the concave portions define a chamber; as best seen in FIGS.8,9.

With respect to claims 85-88, Bianchi et al disclose all the limitations; as best seen in FIGS.8, 9, and as set forth in column 17, lines 1-50.

With respect to claim 94, Bianchi et al disclose an implant (500,500') for implantation in a disc space between adjacent vertebrae, the implant formed of bone and comprising: a first end (501) having a tool engagement recess and an opposite second end (503), a first bone engaging surface and an opposite second bone engaging surface (FIGS 8,9) a first side wall disposed between the first end and the second end and extending from the first bone engaging surface to the second bone engaging surface; a second side wall opposite the first side wall, wherein the implant has a generally rectangular cross section; as set forth in column 8, lines 43-51.

Art Unit: 3732

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With respect to claims 85-88, Bianchi et al disclose all the limitations; as best seen in FIGS.8, 9, and as set forth in column 17, lines 1-50 and as set forth in column 8, lines 43-51.

## Response to Amendment

In response to applicant's argument that Bianchi et al did not teach of a "first generally planar surface and a second generally planar surface and a concave surface there between" or "a first side wall disposed between the lower and upper bone engaging surface and which also has a concave surface positioned between two generally planar surfaces" or "a generally rectangular cross-section transverse to the longitudinal axis"; applicant's attention is directed to Bianchi et al, column 8, lines 43-51.

Bianchi et al stated that, "side wall 506 may include upper and lower flattened portions to stabilize the dowel by neutralizing any rotational torque that may be induced by pressure on the sidewall. This could be achieved by reducing height H of the sidewall 505, by filing or other means".

Therefore, the rectangular shape and the planar sidewalls, as claimed by applicant, are fully disclosed by Bianchi et al.

Furthermore, Applicant has presented no argument which convinces the examiner that the particular configuration of the spacer is significant or is anything more than one numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing mating surfaces in the spacer of Bianchi et al. See In re Dailey, 149 USPQ 47 (CCPA 1976).

Art Unit: 3732

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## Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene April 4, 2003

PEDRO PHILOGENE